

**REMARKS**

This is in response to the Office Action mailed on December 7, 2005, in which claims 14, 15, 17-19, and 29-33 were rejected under 35 U.S.C. § 102(b) as being anticipated by Yokokoji et al. (U.S. Pat. No. 4,212,299); claims 14-15, 17-19, and 29-33 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Yokokoji et al.; and claims 23-26 and 34-38 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Yokokoji et al. in view of Leunberger (U.S. Pat. No. 5,314,421). The Examiner also responded to Applicant's arguments. With this Amendment, claims 14, 23, and 31-33 have been amended. In reliance on the following remarks, the present application with pending claims 14, 15, 17-19, 23-26, and 28-38 is in condition for allowance, and reconsideration and notice to that effect is respectfully requested.

In the Office Action, claims 31-33 were rejected under 35 U.S.C. § 102(b) as being anticipated by Yokokoji et al. The Office Action asserted that claims 31-33 recite method limitations in a product claim. Claims 31-33 have been amended to structurally limit the product claim. Claim 31 has been amended to require that edges of the second film are coupled to edges of the first film. Claim 32 has been amended to require that edges of the first film are welded to edges of the second film. Claim 33 has been amended to require that the second film is ultrasonically sealed to the first film. Claims 31-33 thus structurally limit the product claim. Thus, the rejections to claims 31-33 under 35 U.S.C. § 102(b) should be withdrawn and claims 31-33 allowed.

In the Office Action, independent claim 14 was rejected under 35 U.S.C. § 102(b) as being anticipated by Yokokoji et al. and under 35 U.S.C. § 103(a) as being unpatentable over Yokokoji et al. Independent claim 23 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Yokokoji et al. in view of Luenberger. These rejections will be addressed collectively.

Claims 14 and 23 have been amended to require that the pyrogen-free sterilized bag has been heated to at least approximately 253° Celsius for at least approximately 30 minutes for sterilization and pyrogen removal.

As set forth in the MPEP, a "claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference"

(MPEP 2131). To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). (See MPEP 2142).

Yokokoji et al. do not disclose, teach or suggest a pyrogen-free (i.e., free of bacterial toxin) and sterilized bag. Accordingly, Yokokoji et al. cannot anticipate the presently claimed subject matter under 35 U.S.C. § 102 or render it obvious under 35 U.S.C. § 103.

More specifically, Yokokoji et al. merely mention high thermal resistance of polymer materials such as PTFE, PFA, and ETFE in the context of welding and thermal sticking. “The PFA has a high melting point of 302° to 310° C so that the heat sealing temperature is still higher...” and “While, the ETFE has an adequate melting point of 265° to 270 °C so that it is durable in the sterilization...from wet thermal sterilization at 121 °C for 20 minutes to dry sterilization at 135 ° to 200 °C, without causing the thermal sticking of inner layer films (ETFE).” (Col. 3, lines 6-9, 41-50).

Applicants submit that heat sealing a bag is not the same as heat sterilizing the entire lining of a polymeric bag to result in a pyrogen-free sterilized product. Yokokoji et al. do not disclose, teach, or suggest heating a bag to at least approximately 253° Celsius for at least approximately 30 minutes to ensure that the bag is pyrogen-free and sterilized. By contrast, amended independent claims 14 and 23 require that the bag is heated to at least approximately 253° Celsius for at least approximately 30 minutes to ensure that the bag is pyrogen-free and sterilized. As disclosed in the specification, “...current requirements by the FDA for the sterilization and removal of pyrogen from containers, bags, etc. includes that the interior lining being heated to at least 253° Celsius.” (Para. [0040], lines 22-24).

Therefore, independent claims 14 and 23 are in condition for allowance and the rejections under 35 U.S.C. § 102(b) and 35 U.S.C. § 103(a) should be withdrawn. Moreover, since claims 14 and 23 are in condition for allowance, the rejections to claims 15, 17-19, 24-26, and 28-38, which depend therefrom should be withdrawn as well and claims 15, 17-19, 24-26, and 28-38 allowed.

**Conclusion**

In view of the foregoing, pending claims 14, 15, 17-19, 23-26, and 28-38 are in condition for allowance. Notice to that effect is respectfully requested.

Respectfully submitted,

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